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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/854,280      | 05/10/2001  | Jian Chen            | P1381R1C2           | 8242             |

9157 7590 02/25/2003

GENENTECH, INC.  
1 DNA WAY  
SOUTH SAN FRANCISCO, CA 94080

EXAMINER

JIANG, DONG

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1646

DATE MAILED: 02/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/854,280

Applicant(s)

CHEN ET AL.

Examiner

Dong Jiang

Art Unit

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 29 October 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 61-72 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 61-72 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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### DETAILED OFFICE ACTION

Applicant's amendment in paper No. 12, filed on 29 October 2002 is acknowledged and entered. Following the amendment, claims 61-65, 70 and 71 are amended, and the new claims 72-78 are added.

Applicant's supplemental amendment in paper No. 13, filed on 23 January 2003 is acknowledged and entered. Following the amendment, claims 73-78 are canceled, and claims 61 and 71 are amended.

Currently, claims 61-72 are pending and under consideration.

#### Withdrawal of Objections and Rejections:

The provisional obviousness-type double patenting rejection of claims 62-67 as being unpatentable over claims 54, 76, 80, 81, 85 and 86 of copending Application No. 09/311,832 is moot as the applicant has canceled the conflicting claims in '832.

The rejection of claims 70 and 71 under 35 U.S.C. 112, second paragraph, as being indefinite is withdrawn in view of applicant's amendment.

The scope rejection of claims 61 and 68-71 under 35 U.S.C. 112, first paragraph is withdrawn in view of applicant's amendments.

#### Rejections Over Prior Art:

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

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Claims 61-63 and 68-72 are rejected under 35 U.S.C. 102(e) as being anticipated by Ebner et al., US 2003/0003545.

Ebner discloses a polynucleotide sequence, SEQ ID NO:28, which is 99.8% identical to the nucleotides 50-640 of SEQ ID NO:4 of the present invention, and encodes a polypeptide of IL-21 (SEQ ID NO:29) having 100% sequence identity to the amino acid sequence of SEQ ID NO:3 of the present invention (see appended computer printout of sequence search result). The referenced sequence, therefore, anticipates claims 61-63 and 72 as being a nucleic acid comprising DNA at least 95% to the sequence from position 50-640 of SEQ ID NO:4 (claim 61, part (c), for example), or to a nucleic acid encoding amino acid residues 1-197 or 19-197 of SEQ ID NO:3 (claims 62 and 63), or being a nucleic acid encoding amino acid residues 1-197 or 19-197 of SEQ ID NO:3 (claim 72). Further, Ebner teaches a vector comprising said nucleic acid, a host cell thereof, wherein the host cell is a CHO cell, an E.coli, a yeast or a Sf9 cell, and a process for producing the polypeptide encoded by the polynucleotide (page 32, [0184] – [0192]). Therefore, the reference also anticipates claims 68-71.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

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Claims 64-67 are rejected under 35 U.S.C. 102(e) as anticipated by, or, in the alternative, under 35 U.S.C. 103(a) as obvious over Ebner et al., US 2003/0003545.

The teachings of Ebner are reviewed above.

Claims 64-67 are directed to a nucleic acid comprising nucleotide sequence from position 50 to 640, or 104 to 640 of SEQ ID NO:4. The polynucleotide sequence of SEQ ID NO:28 of the prior art is 99.8% identical to the nucleotides 50-640 of SEQ ID NO:4 of the present invention with a single mismatch at the position 385, which does not change the encoded amino acid. As such, it raises a question of a possible sequencing error on the mismatched nucleotide, and the examiner is unable to determine whether the difference between sequences of the prior art and the instant invention is real. The burden shifts to the applicant to provide evidence that the prior art would neither anticipate nor render obvious the claimed invention. Note the case law of *In re Best* 195 USPQ 430, 433 (CCPA 1977).

**Conclusion:**

No claim is allowable.

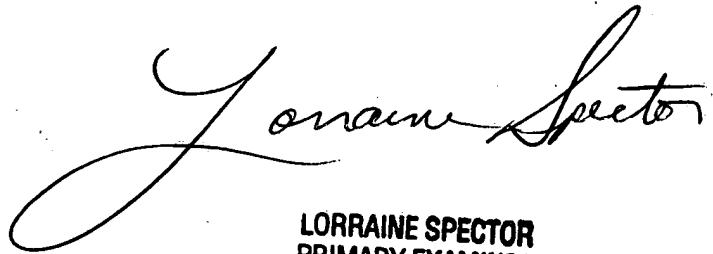
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**Advisory Information:**

Any inquiry concerning this communication should be directed to Dong Jiang whose telephone number is 703-305-1345. The examiner can normally be reached on Monday - Friday from 9:00 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564. The fax phone number for the organization where this application or proceeding is assigned is 703-308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

A handwritten signature in cursive script that reads "Lorraine Spector". The signature is written in black ink and is positioned above a printed name and title.

**LORRAINE SPECTOR  
PRIMARY EXAMINER**

Dong Jiang, Ph.D.  
Patent Examiner  
AU1646  
2/4/03